

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	Upper Body Convective Heat Therapy Device and Method of Making and Using Same
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As the below named inventor(s), I/we declare that:

This declaration is directed to:

- ☒ The attached application, or
☐ Application No. _____ filed on _____
☐ as amended on _____ (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/ we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the National or PCT International filing date of the continuation-in-part application.

All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

FULL NAME OF INVENTOR(S)

Inventor one: Clifford E. GAMMONS

Signature: _____ Citizen of: USA

Inventor two: Joseph G. JONES

Signature:  Citizen of: USA

Inventor three: _____

Signature: _____ Citizen of: _____

Inventor four: _____

Signature: _____ Citizen of: _____

☐ Additional inventors are being named on _____ additional form(s) attached hereto.

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1460.

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Express Mail Number: EV 317317060 US
Docket Number: 27230.03

PTO/SB/81 (06-03)

Approved for use through 11/30/2005. OMB 0651-0035

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**POWER OF ATTORNEY
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CORRESPONDENCE ADDRESS
INDICATION FORM**

Application Number	
Filing Date	
First Named Inventor	GAMMONS, et al.
Title	Upper Body Convective Heat Therapy Devic...
Art Unit	
Examiner Name	
Attorney Docket Number	27230.03

I hereby appoint:

- ☒ Practitioners at Customer Number
OR
☐ Practitioner(s) named below:

Name	Registration Number

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I am the:

☐ Applicant/Inventor.

☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name

Adroit Development, Inc., Clifford Eugene Gammons, Vice President

Signature

Clifford Eugene Gammons

Date

2-9-04

Telephone

865-458 8600

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

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If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Adroit Development, Inc.

Application No./Patent No.: _____ Filed/issue Date: _____

Entitled: Upper Body Convective Heat Therapy Device and Method of Making and Using Same

Adroit Development, Inc., a corporation of Tennessee

(Name of Assignee)

(Type of Assignee, e.g. corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest.
The extent (by, percentage) of its ownership interest is _____ %
in the patent application/patent identified above by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☒ Copies of assignments or other documents in the chain of title are attached.
[NOTE: A separate copy (i.e., the original assignment document or a true copy of the original document) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

2-9-04
Date

Telephone number

Clifford Eugene Gammons

Typed or printed name
Clifford Eugene Gammons
Signature

Vice President
Title

Express Mail Number: EV 317317060 US
Docket Number: 27230.03

PTO/SB/81 (06-03)
Approved for use through 11/30/2005. OMB 0651-0035

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POWER OF ATTORNEY and CORRESPONDENCE ADDRESS INDICATION FORM	Application Number	
	Filing Date	
	First Named Inventor	GAMMONS, et al.
	Title	Upper Body Convective Heat Therapy Devic...
	Art Unit	
	Examiner Name	
	Attorney Docket Number	27230.03

I hereby appoint:

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OR

☐ Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

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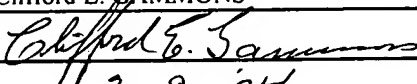
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I am the:

☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/196).

SIGNATURE of Applicant or Assignee of Record

Name	Clifford E. GAMMONS		
Signature			
Date	2-9-04	Telephone	

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 2 forms are submitted.

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Application Number	
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First Named Inventor	GAMMONS, et al.
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Name	Registration Number

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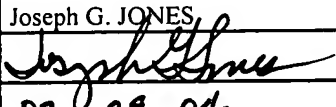
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I am the:

- ☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name	Joseph G. JONES		
Signature			
Date	02-09-04	Telephone	

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial Number: N/A
Filing Date: N/A
Parent Serial Number: 09/916,353
Parent Filing Date: July 27, 2001
Applicant: Clifford Gammons, et al.
Title: Upper Body Convective Heat Therapy Device and Method of Making and Using Same
Docket Number: 27230.03
Declarant: Kelley Patten

DECLARATION OF KELLEY PATTEN UNDER 37 C.F.R. § 1.132.

1. I, Kelley Patten, declare as follows, under penalty of perjury.
2. I hold a B.S. degree from North Carolina State University, Raleigh, North Carolina, awarded in 1997.
3. I first worked for Adroit Medical Systems in Loudon, Tennessee, in 1993, and again in 1994 and 1995 while working toward my degree. In October 2002 I became the Strategic Planning Coordinator for Adroit Medical Systems and still hold that position. During my employment by Adroit Medical Systems I have assisted in the manufacturing assembly of hypothermia and hyperthermia systems, in writing, maintaining and implementing all quality procedures, and in documentation control. While employed by Adroit Medical Systems I became familiar with hypothermia and hyperthermia systems manufactured by Adroit Medical Systems and their competitors.
4. I have reviewed Application Serial Number 09/916,353, filed on July 27, 2001, and titled "Upper Body Convective Heat Therapy Device and Method of Making and Using Same."
5. I have reviewed United States Patent Numbers 5,674,269, ("the '269 patent" by Augustine), 6,102,936, ("the '936 patent" by Augustine), 5,443,488, ("the '488 patent" by Namenye, et al.), 5,165,400, ("the '400 patent" by Berke), and 5,246,656 ("the '656 patent" by Stephenson).
6. Among the heat therapy devices with which I was familiar prior to the filing date of Application Serial Number 09/916,353, were devices of the type shown in the patents listed in paragraph 5.

7. I have reviewed the U.S. Patent and Trademark Office action, Paper Number 5, which contains the following statement on page 3:

It would have been obvious to one of ordinary skill in the art at the time of the invention to attach the device of Augustine ('269) to a base sheet in order to prevent the device from unintentional movement during use.

The above statement is incorrect, in view of the state of the heat therapy device art as of the filing date of Application Serial Number 09/916,353. One skilled in the art would not have made that combination as of the filing date, for the following reasons:

Modifying the inflatable thermal care apparatus **100** disclosed by Augustine '269 by adding a base sheet would destroy the intended function of the Augustine '269 apparatus **100** and render the apparatus **100** inoperable.

Augustine '269 discloses an inflatable thermal care apparatus **100**, which is a U-shaped tube **102** formed around the patient with a user-configurable access panel **118** covering the patient. Augustine '269, Col. 3, line 62 to Col. 4, line 21, Fig. 1. Augustine '269 states that the panel **118** "is secured to the sides **110**, **112** and spans the patient **104**" and "is secured to the sides **110**, **112** by double-sided adhesive tape." Augustine '269, Col. 4, lines 19-26. Augustine '269 discloses that that the apparatus **100** is used by first, placing the patient **104** "supine on a flat surface **105**, such as a hospital bed. Then, the apparatus **100** is placed over the patient **104**, with the sides **110**, **112** generally parallel to the patient's sides. The access panel **118** is centered over the patient's torso." Augustine '269, Col. 37, lines 30-34.

Because the panel **118**, which is above the patient **104**, is attached to the sides **110**, **112** of the U-shaped tube **102** and covers the patient **104**, the apparatus **100** must be placed over the patient **104** as described in Augustine '269. Accordingly, the Augustine '269 apparatus **100** requires an opening through which the body of the patient **104** can be placed inside the apparatus **100**. That opening is on the bottom side of the apparatus **100**.

Placing a base sheet on the bottom of the apparatus **100** of Augustine '269 would render the apparatus **100** inoperable because the apparatus **100** could not be placed around a patient **104** in a manner contemplated by Augustine '269 or by anyone else in a manner that would be practical to achieve. The only remaining opening in the apparatus **100** if so modified would be a narrow gap between the sides **110**, **112** of the U-shaped tube **102** and between the panel **118** and the added base sheet.

Accordingly, there was no reason apparent to one skilled in the art as of the filing date of Application Serial Number 09/916,353 "to attach the device of Augustine ('269) to a base sheet" as suggested by the Examiner because to do so would cover the opening in the device through which the patient is introduced to the device and prevent the device of Augustine '269 from being usable for its intended purpose.

Declaration of K l l y Patten

8. I have reviewed the U.S. Patent and Trademark Office action, Paper Number 5, which contains the following statement on page 3:

Augustine ('269) fails to show a means for securing said means for containing in a fixed position adjacent to an upper body member, which is equivalent to that disclosed by the applicant in the specification. However, Augustine ('936) does show an equivalent means for securing (flap 70) said means for containing (10) in a fixed position. It would have been obvious to one of ordinary skill in the art at the time of the invention to include the means for securing in the device of Augustine ('269) in order to prevent unintentional movement of the apparatus.

The above statement is incorrect, in view of the state of the heat therapy device art as of the filing date of Application Serial Number 09/916,353. One skilled in the art would not have made that combination as of the filing date, for the following reasons:

Augustine '936, in combination with Augustine '269, does not disclose all the elements required by Claim 21 of the Application. A reading of Application Serial Number 09/916,353 indicates that the "means for securing said means for containing in a fixed position adjacent to an upper body member" of Claim 21 is accomplished by securing the tube **102** "to the base sheet **104** in four places. The tube **102** is attached by securing the seam **222** on both sides of the inlet collar **108** to the base sheet **104**. . . . The tube **102** is secured to the base sheet **104** by the two securing tabs **206**, **306** protruding from the tube **102**. Each securing tab **206**, **306** is folded under its respective tube leg **302**, **304** and secured to the base sheet **104**." Application Serial Number 09/916,353. Because the "base sheet **104** is placed under the head and shoulders of the patient **110**, who is lying on a table or bed **114**," the base sheet **104** is crucial to securing the tube **102** "in a fixed position adjacent to an upper body member." Application Serial Number 09/916,353.

A reading of Augustine '936 does not disclose the equivalent of a base sheet that is secured to pad **10**. The Augustine '936 patent states, at column 6, lines 8-27:

Other features of our inflatable thermal pad **10** may be understood with reference to FIG. 2A. In this regard, one or more flexible non-inflatable (or partially-inflatable) sections **70** ("flaps" or "drapes") formed integrally with the pad **30** may be provided along the periphery **14**. For example, in FIG. 2A, two flaps **70** are shown, one on each side of the end portion **23**. With respect to the flap **70**, it includes an outer edge **71** along either or both sides of which one or more traces of adhesive **75** (or double-sided adhesive tape with a release liner) may be placed. The flap **70**, and any others like it that may be provided on the pad **10**, has a one of two functions. First, it can be disposed upwardly over the upper surface **15** of the top layer **12**, positioned over the body of a person supported on that surface in order to assist in the trapping of air and the retention of warmth about the person's body. The second function includes folding the one or more flaps downwardly, beneath the bottom surface **13** so that the pad **10** can be anchored by the trace of adhesive **75** to an apparatus or structure on which the pad **10** is supported.

As identified in Augustine '936, the flaps **70** have two independent functions. First, the flaps **70**, when folded over the patient, trap and retain warm air about the patient. Second, the flaps **70**, when folded down and adhered to a supporting surface, anchor the thermal pad **10** to the supporting surface. When used for the second function, the flaps **70** of Augustine '936 are equivalent to the securing tabs **206, 306** discussed in the Application; however, Augustine '936 does not disclose a base sheet separate from the table or bed upon which the patient is lying as is described in the Application. Further, neither Augustine '269 nor Augustine '936 disclose attaching a base sheet directly to a tube.

Accordingly, "the means for securing in the device of Augustine ('269)" are not the same as the "means for securing" the device of Application Serial Number 09/916,353 because the structures described in the Application are not found in Augustine '269 or Augustine '936.

9. I have reviewed the U.S. Patent and Trademark Office action, Paper Number 5, which contains the following statement on page 4:

It would have been obvious to one of ordinary skill in the art at the time of the invention to use Y-shaped slits as the apertures in the Augustine invention in order to allow the valve flaps to automatically close under the influence of external pressures, such as when the patient is touching the device, and prevent direct exposure of the patient to the air (cols. 1-2, Stephenson (5,246,656), which is expressly incorporated in Naménye).

The above statement is incorrect, in view of the state of the heat therapy device art as of the filing date of Application Serial Number 09/916,353. One skilled in the art would not have made that combination as of the filing date, for the following reasons:

Stephenson, in combination with Augustine '269 and Augustine '936, does not disclose all the elements required by Claims 8, 19, and 27 of the Application. A reading of Application Serial Number 09/916,353 shows that Claim 8 includes the element of a "plurality of exhaust ports are a plurality of slits," Claim 19 includes a "plurality of exhaust ports include a plurality of slits," and Claim 27 states that that "each one of said plurality of exhaust ports is a slit." Further, Claims 8 and 19 include the limitation that "each of said plurality of slits [is] positioned substantially parallel to a longitudinal axis," and Claim 27 includes the limitation that "said slit oriented [is] substantially parallel to a longitudinal axis."

One skilled in the art would know a slit is a straight, lengthwise incision or cut. This definition of a slit is consistent with the way Application Serial Number 09/916,353 uses the term. This definition is also consistent with Stephenson, which discloses a Y-shaped orifice made of three slits joined at a common point. Stephenson teaches a tool **28, 32** for cutting orifices **24** in a temperature regulating blanket **10**. See Stephenson, Col. 4, lines 1-7. Stephenson, at column 4, lines 52-58, states, with respect to the orifices,

With reference to FIG. 9, the desired air flow control orifice **24** is shown. The orifice **24** consists of a plurality of flexible valve flaps **54** formed of the material of the film **40** as defined by the slits **56** which are the slits cut in the film by the punch intersecting edges **46**. In FIG. 9 the width of the slits **56** is exaggerated for purpose of illustration.

One skilled in the art would not say that the Y-shaped orifice of Stephenson is the same as the slit claimed in Application Serial Number 09/916,353 because the claimed slits are oriented "substantially parallel to a longitudinal axis," which necessitates that the slits be singly disposed and not in groups of three as would be with a Y-shaped orifice. Accordingly, the references do not disclose slits as claimed in Application Serial Number 09/916,353 because "Y-shaped slits" are not the same as straight slits.

10. I have reviewed the U.S. Patent and Trademark Office action, Paper Number 5, which contains the following statement on page 5:

However, Berke fails to show attaching said first tube sheet and second tube sheet to a base sheet and fixing one end of the cover sheet to the first leg. Augustine ('936) shows a similar thermal device wherein the first tube sheet (12) and second tube sheet (13) are attached to a base sheet (col 6, lines 23-26). It would have been obvious to one of ordinary skill in the art at the time of the invention to attach the device of Berke to a base sheet in order to prevent the device from unintentional movement during use. Augustine ('269) shows a similar thermal device wherein the cover sheet (118) is attached to the first leg (110) by adhesive and extends to the second leg. It would have been obvious to one of ordinary skill in the art at the time of the invention to attach the cover sheet to the first leg to prevent unintentional removal from the patient during use.

The above statement is incorrect, in view of the state of the heat therapy device art as of the filing date of Application Serial Number 09/916,353. One skilled in the art would not have made that combination as of the filing date, for the following reasons:

Initially, the statement that the thermal device of Augustine '936 is similar to the device of Berke is not correct. The device of Augustine '936 is a thermal blanket upon which a patient lies and which has the capability of draining fluids away from the patient. Augustine '936, Col. 3, lines 17-47. The device of Berke is a U-shaped tube in which the legs are placed on either side of the patient. Berke, Fig. 1. A reading of Augustine '936 and Berke indicate that the respective devices solve different problems. Augustine '936, Col. 2, lines 14-17; Berke, Col. 3, lines 17-36.

The statement that the Augustine '936 has a "first tube sheet (12) and second tube sheet (13)" is not correct because reference numeral **12** is described in Augustine '936 as the top layer and numeral **13** is described as the bottom layer. Augustine '936, Col. 6, line 8. Further, the apparatus of Augustine '936 is an inflatable thermal pad **10** having "at least two layers of material that are brought together at a

periphery." Augustine '936, Col. 4, lines 10-12. Accordingly, the pad **10** is not in the shape of a tube or is otherwise cylindrical. Augustine '936, Fig. 1.

Additionally, the statement that it would be obvious "to attach the device of Berke to a base sheet" is not correct. A reading of Berke does not indicate any suggestion or teaching that a base sheet should be attached to the device of Berke. Likewise, a reading of Augustine '936 does not indicate any suggestion or teaching that a base sheet should be attached to a device such as disclosed by Berke. Augustine '936 discloses flaps **70** attached to the pad **10**, in which a function of the flaps **70** "includes folding the one or more flaps downwardly, beneath the bottom surface **13** so that the pad **10** can be anchored by the trace of adhesive **75** to an apparatus or structure on which the pad **10** is supported." Augustine '936, Col. 6, lines 26-27. Augustine '936 does not disclose a base sheet separate from the apparatus or structure on which the pad **10** is placed. Accordingly,

Accordingly, there was no reason apparent to one skilled in the art as of the filing date of Application Serial Number 09/916,353 "to attach the device of Berke to a base sheet" because none of the references suggest or teach such an addition.

Finally, the statement regarding that the characterization of the cover sheet **118** of Augustine '269 is not correct. Augustine '269 states that the access panel **118** "is secured to the sides **110**, **112** and spans the patient **104**" and "is secured to the sides **110**, **112** by double-sided adhesive tape." Augustine '269, Col. 4, lines 19-26. By necessity, the access panel **118** must be connected on both sides **110**, **112** because either side of the panel **118** is used to provide access to the patient by folding a portion of the panel **118** away from the middle toward the sides **110**, **112**. Augustine '269, Col. 5, lines 14-47. Further, by not attaching both sides of the access panel **118** to the sides **110**, **112**, then air would be allowed to escape which would not allow the device **100** to perform its function of maintaining the temperature of the patient. Therefore, the statement that it would be obvious "to attach the cover sheet to the first leg" is not correct because it implies that the cover sheet of Augustine '269 is to be attached to only one leg, which is contrary to the disclosure in Augustine '269 and would render the device of Augustine '269 unsuitable for its intended purpose.

Accordingly, there was no reason apparent to one skilled in the art as of the filing date of Application Serial Number 09/916,353 "to attach the cover sheet to the first leg" because none of the references suggest or teach a cover sheet being attached to one leg and extending to the second leg.

Respectfully submitted,


Kelley Patten